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Registration Decision RD2012-22

Sulphur

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Registration Decision for Sulphur

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Hollysul Technical Sulphur and Grotek Ascend Vaporized Sulphur, containing the technical grade active ingredient sulphur, to control powdery mildew caused by various pathogens on vegetables, small fruit, and ornamentals in greenhouses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-01, *Sulphur*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for sulphur and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-01. This decision is consistent with the proposed registration decision stated in PRD2012-01.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2012-01, *Sulphur* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Sulphur?

Sulphur is the oldest known pesticide. It is a low cost, multi-site fungicide that is widely used to control powdery mildew on many crops. Sulphur is the active ingredient in Grotek Ascend Vaporized Sulphur. It is generally accepted that the efficacy of sulphur for powdery mildew control is related to contact and vapour activity. Sulphur inhibits germination of spores of the powdery mildew fungi, although the mode of action is uncertain. Sulphur vapour may be absorbed into lipids in spores and metabolism by the fungi may lead to hydrogen sulphide (H_2S) production and blocking of respiration.

Health Considerations

Can Approved Uses of Grotek Ascend Vaporized Sulphur Affect Human Health?

Grotek Ascend Vaporized Sulphur is unlikely to affect your health when the product is used according to the label directions.

Potential exposure to Grotek Ascend Vaporized Sulphur may occur when handling and applying the product or through the diet (food). When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Grotek Ascend Vaporized Sulphur consists of 99.9% elemental sulphur, a previously registered technical active ingredient. Sulphur is of low acute toxicity by the oral, dermal, and inhalation routes. Sulphur is also considered to be a mild skin irritant, moderately irritating to the eyes, and non-sensitizing.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The proposed use for Grotek Ascend Vaporized Sulphur is as a fungicide to be applied via vaporizers to greenhouse vegetables, small fruit, and ornamentals. This use should not result in additional exposure beyond currently registered food uses of sulphur. Vaporized sulphur is not expected to come into contact with any water supplies. Therefore, the use of Grotek Ascend Vaporized Sulphur is not expected to result in dietary risk from consuming food or drinking water.

Risks in Residential and Other Non-Occupational Environments

Risks to residential and other non-occupational environments are not of concern when Grotek Ascend Vaporized Sulphur is used according to label directions, which include protective measures.

Grotek Ascend Vaporized Sulphur is for use in commercial greenhouses. It is not intended for use in residential or non-occupational environments.

Sulphur vaporizers used for the application of Grotek Ascend Vaporized Sulphur are to be turned on only when greenhouses are closed to staff, the public and/or customers. Also, vaporizers are to be used only when greenhouses can be ventilated without exposing bystanders or occupants of adjacent structures to vaporized sulphur. Vaporizers are not to be used if a greenhouse shares a common wall, floor or ceiling with a building inhabited by livestock or humans. Therefore, the use of Grotek Ascend Vaporized Sulphur is not expected to result in any risks to bystanders from vaporized sulphur.

Occupational Risks From Handling Grotek Ascend Vaporized Sulphur

Occupational risks are not of concern when Grotek Ascend Vaporized Sulphur is used according to label directions, which include protective measures.

There is a potential for dermal and inhalation exposure to Grotek Ascend Vaporized Sulphur when filling the sulphur vaporizers, if workers enter the greenhouse during the vaporization process or when performing crop maintenance, harvesting or other activities after vaporization is complete. There is also a potential for inhalation exposure to sulphur dioxide if workers enter the greenhouse during the vaporization process.

The toxicity of sulphur is low by the dermal and inhalation routes of exposure. Workers filling and servicing sulphur vaporizers with Grotek Ascend Vaporized Sulphur would be exposed to similar or lesser amounts of sulphur compared to workers handling currently registered products containing sulphur. Workers filling and servicing sulphur vaporizers are also required to wear similar personal protective equipment (PPE) as workers handling currently registered products. According to the label instructions, sulphur vaporizers are to be operated by a timer or remote switch and greenhouse entrances should be locked and have warning signs during vaporization.

Also, workers are not to enter the greenhouse until vaporization is complete, the greenhouse is thoroughly ventilated, and the re-entry interval (24 hours) on the label has passed, unless the workers are wearing full protective clothing and a self-contained breathing apparatus. Because the application rates for Grotek Ascend Vaporized Sulphur are lower than application rates for currently registered products containing sulphur, the exposure of workers to sulphur when they are performing crop maintenance and harvesting activities is expected to be less than for currently registered products.

Sulphur dioxide can be formed if sulphur is (over-)heated beyond vaporization temperatures. The label for Grotek Ascend Vaporized Sulphur includes instructions for avoiding the formation of sulphur dioxide during the filling of the vaporizers. In addition, the estimated levels of sulphur dioxide formed during vaporization are less than occupational exposure limits included in provincial occupational health and safety regulations.

Therefore, the use of Grotek Ascend Vaporized Sulphur is not expected to result in increased risks from occupational exposures to vaporized sulphur or sulphur dioxide.

Environmental Considerations

What happens when Hollysul Technical Sulphur and Grotek Ascend Vaporized Sulphur is introduced into the environment?

Sulphur and the associated end-use product Grotek Ascend Vaporized Sulphur are to be used in the enclosed space of a greenhouse. The product is applied as a vapour and ultimately vented to the outside in a controlled manner once treatment is completed; the only contact sulphur will have with the environment is at the point of venting. The small amount of vapourized sulphur vented to the outside will dissipate rapidly in air upon release, and result in minimal environmental exposure to non-target organisms.

Value Considerations

What Is the Value of Grotek Ascend Vaporized Sulphur?

Sulphur, the active ingredient in Grotek Ascend Vaporized Sulphur, controls powdery mildew on vegetables, small fruits and ornamentals in greenhouse.

Grotek Ascend Vaporized Sulphur is applied using a sulphur vaporizer in greenhouses to control powdery mildew caused by various pathogens on greenhouse vegetables (tomato, pepper and eggplant), small fruit (strawberry), and greenhouse ornamentals (rose, gerbera, kalanchoe, begonia, hydrangea, snapdragon, African violet, chrysanthemum, phlox and dahlia). To apply the vaporized sulphur, elemental sulphur is loaded into a sulphur vaporizer and the device vaporizes a certain amount of sulphur per hour under a specific operating temperature. Other sulphur products applied as foliar spray or dust are currently registered for above mentioned crops and plants in greenhouses. Grotek Ascend Vaporized Sulphur may provide Canadian greenhouse growers an additional application method of sulphur to control powdery mildew in greenhouses.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Grotek Ascend Vaporized Sulphur to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements, "WARNING – EYE IRRITANT" and "CAUTION – SKIN IRRITANT" have been included on the principal display panel of the label for Grotek Ascend Vaporized Sulphur. The statements, "KEEP OUT OF REACH OF CHILDREN AND UNAUTHORIZED PERSONNEL. Do not inhale dust or vapour. Causes eye irritation and may irritate the skin. Do not get in eyes and avoid contact with the skin. Wear goggles or a face shield, a NIOSH-approved respirator, chemical resistant gloves, a hat, a long-sleeved shirt, long pants and rubber boots when filling, cleaning, and repairing sulphur vaporizers. Do not enter or allow workers to enter into treated areas until 24 hours after application unless wearing a self-contained breathing apparatus, goggles or a face shield, chemical resistant gloves, a hat, a long-sleeved shirt, long pants and rubber boots. Sulphur vaporizers should only be used at times when the greenhouse is closed to staff, public and/or customers. Vaporizers should only be used when a greenhouse can be ventilated without exposing bystanders or occupants of adjacent structures to vaporized sulphur. Vaporizers are not to be used if the greenhouse shares a common wall, floor or ceiling with a building inhabited by livestock or humans.", have been included in the Precautions section of the secondary display panel for Grotek Ascend Vaporized Sulphur.

Additional label precautionary statements for the vaporizers to prevent fires, spillage of molten sulphur, and the formation of sulphur dioxide include, "As device will get very hot, do not touch until cooled down. Do not enclose the vaporizer during operation or block any of the openings as this may cause a fire. Do not overfill the cup beyond 2 cm depth as this may cause the molten sulphur to boil over onto the hot element and cause a fire or gases that are toxic to plants and humans."

Environment

No mitigative measures are required for the registered use of Grotek Ascend Vaporized Sulphur.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-01, *Sulphur)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.